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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/724,292	12/01/2003	Juan Armendariz Borunda	5585-036-999	4513

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EXAMINER	
CHEN, SHIN LIN	
ART UNIT	**PAPER NUMBER**
1632	
MAIL DATE	**DELIVERY MODE**
07/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/724,292	ARMENDARIZ BORUNDA ET AL.	
	Examiner	Art Unit	
	Shin-Lin Chen	1632	

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 May 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22,24-30 and 32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22, 24-30 and 32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' amendment filed on 5-2-07 has been entered. Claim 22 has been amended. Claim 31 has been canceled. Claims 22, 24-30 and 32 are pending and under consideration.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 22, 24-30 and 32 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention and is repeated for the reasons set forth in the preceding Official action mailed on 2-5-07. Applicant's arguments filed 5-2-07 have been fully considered but they are not persuasive.

Applicants cite paragraphs [0063] to [0071] (pages 11-16 of the specification) and argue that a patent need not disclose what is well known in the art and no undue experimentation is required for the claimed invention. Applicants argue that the specification provides enabling disclosure for the invention claimed (amendment, p. 5-14). This is not found persuasive because of the reasons set forth in the preceding Official action mailed 2-5-07. The specification discloses the rat models receiving infusion of Ad5gal vector by iliac vein and shows that the main target organ of the infused adenoviral vector is the liver. The spleen and the lung present a transduction grade lower than 1% and other organs, such as kidney, heart and brain, show no

transduction at all (specification, pages 12-16). The claims encompass treating various fibrotic diseases or disorders in a patient by delivering a recombinant adenoviral vector expressing a therapeutic protein under the control of a promoter to various target organs via various administration routes in vivo. The specification fails to provide adequate guidance and evidence for delivering a recombinant adenoviral vector expressing any therapeutic protein under the control of a promoter via various administration routes in vivo such that sufficient therapeutic protein can be obtained so as to provide therapeutic effects in target organs for treating any fibrotic disease or disorder in a patient.

The state of gene therapy in vivo was unpredictable at the time of the invention. The administration route includes oral administration, intraperitoneal injection, topical administration, intravenous administration, intramuscular injection, and subcutaneous administration etc. As discussed above, the specification discloses that infusion of Ad5gal vector into rats by iliac vein shows that the main target organ of the infused adenoviral vector is the liver. Other organs, such as spleen, lung, kidney, heart and brain, show either very low transduction efficiency or no transduction at all. It appears that when an adenoviral vector is administered via infusion or intravenous administration, most of the adenoviral vector reaches the liver but very little reaches other organs. The specification fails to provide adequate guidance and evidence for whether intravenous administration of an adenoviral vector to a patient could provide sufficient expression of a therapeutic protein in any organ other than the liver in said patient so as to provide therapeutic effect for treating various fibrotic disorders in different organs. The specification also fails to provide adequate guidance and evidence for whether various administration routes of an adenoviral vector to a patient could provide

sufficient expression of a therapeutic protein in any organ, including the liver, in said patient so as to provide therapeutic effect for treating various fibrotic disorders in different organs. In addition, the in vitro data of cultured cells cannot be extrapolated into the success for gene therapy in vivo. There is no evidence of record that shows administration of a recombinant adenoviral vector expressing a therapeutic protein under the control of a promoter or a combination of promoters into a patient via various administration routes can provide therapeutic effects for treating various fibrotic disorders or diseases in said patient. Therefore, one skilled in the art would not know how to use the recombinant adenoviral vector for treating various fibrotic diseases or disorders via various administration routes in vivo.

Further, the claims also encompass using nucleotide sequences encoding various therapeutic proteins for treating various fibrotic diseases or disorders in a patient. However, different therapeutic proteins have different amino acid sequences and their biological functions would differ. The biological function of a protein was unpredictable from mere amino acid sequence at the time of the invention. The specification fails to provide adequate guidance and evidence for whether the claimed therapeutic protein or combination of therapeutic proteins would be able to treat various fibrotic diseases or disorders in different organs in vivo. Thus, one skilled in the art at the time of the invention would require undue experimentation to practice over the full scope of the invention claimed. Claims 22, 24-30 and 32 remain rejected under 35 U.S.C. 112, first paragraph.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (571) 272-0726. The examiner can normally be reached on Monday to Friday from 9:30 am to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for this group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Shin-Lin Chen, Ph.D.

SHIN-LIN CHEN
PRIMARY EXAMINER